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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)



(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference GP040001	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/KR2004/000054	International filing date(day/month/year) 14 JANUARY 2004 (14.01.2004)	Priority date (day/month/year) 14 JANUARY 2003 (14.01.2003)	
International Patent Classification (IPC) or national classification and IPC IPC7 C12N 5/00, C12N 5/06, A61K 9/00			
Applicant YONSEI UNIVERSITY et al			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 12 AUGUST 2004 (12.08.2004)	Date of completion of this report 04 JANUARY 2005 (04.01.2005)
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/000054

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☒ This report is based on translations from the original language into the following language English which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☒ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished

- ☒ the description:
- pages 1-24 as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____

- ☒ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* 25-27 received by this Authority on 15 November 2004
- pages* _____ received by this Authority on _____

- ☒ the drawings:
- pages 1/9-9/9 as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____

- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☒ the claims, Nos. 3
- ☐ the drawings, sheets _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/000054

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,2,4-13	YES
	Claims		NO
Inventive step (IS)	Claims	1,2,4-13	YES
	Claims		NO
Industrial applicability (IA)	Claims	1,2,4-13	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following document has been considered for the purpose of this report:

D1 : J. Oral. Maxillofac. Surg.(Weng, Y et al.), vol.59(2), pp.185-190, Feb. 2001.

I. Novelty and Inventive step

The present invention relates to a 1 to 3 mm-sized scaffold for regenerating a biological tissue, covered with a semi-permeable membrane; and a method for preparing a scaffold covered with a semipermeable membrane, comprising loading one or more scaffolds into a mold with a predetermined form and size.

The cited document D1 discloses a biodegradable scaffold formed in the shape of the human mandible condyle, seeded with osteoblasts resuspended in calcium alginate, a semi-permeable membrane forming reagent.

Compared with the present invention, none of the above-mentioned prior art documents disclose the 1 to 3 mm-sized scaffolds covered with a semi-permeable membrane; and that the scaffold has the morphology of a biological tissue of interest by cross-linking the small-sized scaffolds, thereby allowing uniform proliferation of tissue cells throughout the whole scaffold.

Therefore, the subject matter of the present claims 1,2,4-13 is considered to be novel and to involve an inventive step under PCT Article 33(2) and (3).

II. Industrial applicability

The subject matter of claims 1,2,4-13 is considered to be industrially applicable (PCT Article 33(4)).

What is claimed is:

1. (amended) A scaffold for regenerating a biological tissue by seeding tissue cells onto the scaffold and growing the tissue cells on the scaffold; comprising a semi-permeable membrane formed on an outer surface thereof and is 1 to 3mm in size.

2. The scaffold as set forth in claim 1, wherein the semi-permeable membrane is made of one selected from among alginates, polysaccharides, chitosan, agar powder and gelatin.

3. (Deleted)

4. A method for preparing a scaffold comprising a semi-permeable membrane, comprising:

loading one or more scaffolds into a mold with a predetermined form and size; and

adding a mixture of a semi-permeable agent and a cross-linking agent to the mold and cross-linking the semi-permeable agent to form the semi-permeable membrane on an outer surface of each of the scaffolds.

5. The method as set forth in claim 4, wherein the semi-permeable agent is selected from among alginates, polysaccharides, chitosan, agar powder and gelatin.

6. The method as set forth in claim 4, wherein the cross-linking agent is selected from among calcium chloride, tripolyphosphate and glutaraldehyde.

5 7. The method as set forth in claim 4, wherein the mold is made of Teflon.

8. A method of preparing a biological tissue, comprising:
seeding cells obtained from a tissue to be regenerated onto one or more scaffolds;

10 loading the scaffolds seeded with the tissue cells into a molding container with a predetermined form and size;

adding a semi-permeable agent and a cross-linking agent to the molding container and forming a semi-permeable membrane on an outer surface of each of the scaffolds loaded in the molding container to interconnect the scaffolds; and

15 introducing nutrients into the scaffolds interconnected with the cross-linking agent, thus proliferating the tissue cells.

20 9. The method as set forth in claim 8, wherein the semi-permeable agent is selected from among alginates, polysaccharides, chitosan, agar powder and gelatin.

10. The method as set forth in claim 8, wherein the cross-

linking agent is selected from among calcium chloride, tripolyphosphate and glutaraldehyde.

11. The method as set forth in claim 8, wherein the mold is made of Teflon.

5 12. A biological tissue prepared using the scaffold comprising the semi-permeable membrane according to any one of claims 1 to 2.

 13. A biological tissue prepared by the method according to any one of claims 8 to 11.